

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

The effect of virtual counseling and educational booklets on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Protocol summary

Study aim

Comparison of the effect of virtual counseling and educational booklet on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Design

In this study, two intervention groups including virtual counseling and educational booklets and a control group with a parallel design will participate. Then, the samples will be randomly assigned to a group of 45 people for the intervention1 (receiving virtual counseling), a group of 45 for the intervention2 (receiving a training book) and a control group of 45 using 6 permutation blocks.

Settings and conduct

Mothers with premature babies discharged from the Neonatal Intensive Care Unit of Fatemieh Hospital in Hamedan who meet the inclusion criteria will be randomly allocated into three groups. The first group will receive virtual counseling, the second group will receive an educational booklet, and the third group will be the control group. Questionnaires will be completed before the intervention and 2 weeks later.

Participants/Inclusion and exclusion criteria

A healthy single baby with a birth age of 32-36 weeks

Intervention groups

Virtual consulting group: counseling sessions will be held in 4 sessions of 20-30 minutes 2 times a week with an interval of 3 days online. Educational booklet group: In this group, after completing the questionnaires at the time of discharge, the educational booklet for post-discharge care of premature babies is given to the mothers, and for 2 weeks after completing the first questionnaire, the self-efficacy and anxiety questionnaires are repeated by the people of this group. The group will be completed. Control group: In this group, the questionnaires will be completed electronically at the time of discharge and 2 weeks after

that.

Main outcome variables

self-efficacy and anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221217056842N2**

Registration date: **2023-12-03, 1402/09/12**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-03, 1402/09/12**

Update count: **0**

Registration date

2023-12-03, 1402/09/12

Registrant information

Name

Mansoureh Refaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0535

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-01, 1402/09/10

Expected recruitment end date

2024-08-31, 1403/06/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of virtual counseling and educational booklets on self-efficacy and anxiety of mothers with premature babies discharged from the neonatal intensive care unit

Public title

The effect of virtual counseling and educational booklet on self-efficacy and anxiety of mothers with premature babies discharged from hospital

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

preterm birth between 32 and 36 week singleton pregnancy Ability to read and write in persian Speaking in Persian Ability to use online software Internet access Living with spouse

Exclusion criteria:

Abnormalities in the baby Participation in training courses related to the topic of the research Medical illnesses and drug use History of any mental disorder The occurrence of unfortunate and stressful events in the last 6 months (death of relatives, divorce, serious accidents, etc.)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **135**

Randomization (investigator's opinion)

Randomized

Randomization description

The sequence of random allocation will be determined by one of the researchers based on the permutation blocking method in three groups A, B and C using RAS(Random allocation software) software. The determined sequence will be written from beginning to end and placed in the sealed envelopes. Then, each envelope is assigned a number corresponding to the number of samples, from 1 to 135. Then the numbered envelopes are given to another researcher who is not aware of the random allocation process. Then the samples are placed in the control, virtual counseling and educational booklet groups in the order of arrival and in the order of the number of envelopes. After collecting the data, the data is entered into the software based on the number and group A, B and C. Thus the statistical analyst will not be aware of the type of assigned group.

Blinding (investigator's opinion)

Single blinded

Blinding description

After collecting the data, the data is entered into the software based on the number and group A, B and C and thus the statistical analyst will not be aware of the type of assigned group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics Committees of Hamadan University Of Medical Sciences

Street address

Shahid Fahmideh Ave, Hamadan Town

City

Hamadan

Province

Hamadan

Postal code

۶۵۱۷۸۳۸۶۷۸

Approval date

2023-11-25, 1402/09/04

Ethics committee reference number

IR.UMSHA.REC.1402.563

Health conditions studied**1****Description of health condition studied**

self-efficacy

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

Primary outcomes**1****Description**

self-efficacy

Timepoint

Before Intervention, two weeks later

Method of measurement

Perceived Maternal Parenting Self-efficacy (PMPS-E)

2

Description

Anxiety

Timepoint

Before Intervention, two weeks later

Method of measurement

The State-Trait Anxiety Inventory (STAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the first intervention group (virtual counseling), the time and application needed to hold virtual counseling sessions will be informed by phone. Individual counseling sessions will be held in 4 sessions of 20-30 minutes, 2 times a week with an interval of 3 days, online in the MEET application. The first counseling session will be held in the first three days after discharge (as agreed with the participant).

Category

Lifestyle

2

Description

Intervention group: In the second intervention group, after completing the questionnaires at the time of discharge, the mothers will be given a educational booklet. Self-efficacy and anxiety questionnaires will be completed again 2 weeks later by the people of this group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Mansoureh Refaei

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Pasdaran Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Dr. Reza Shokoohi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hamedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Mansoureh Refaei

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available